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COMPARATIVE STUDY BETWEEN SURGICAL TREATMENT AND DILTIAZEM 2% GEL APPLICATION IN THE MANAGEMENT OF CHRONIC ANAL FISSURE

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ABSTRACT

Introduction: The surgical intervention on chronic anal fissure is still the first line of treatment for this disease. The importance of this research lies in finding a new treatment for one of the most common anal lesions, and to choose a safe and effective method in the treatment of chronic anal fissure, avoiding the risks of anesthesia and surgery. **Objective:** To compare the surgical treatment (Lateral Internal Sphincterotomy) and topical treatment (Diltiazem Gel 2%), in terms of the ability to heal, studying the degree of symptoms regression after the treatment (bleeding/pain), and studying the incidence of gas / fecal incontinence. **Materials and Methods:** A prospective pilot study, which included 60 patients divided into two groups equally, Group A (30 patients who underwent surgical treatment), Group B (30 patients who underwent topical drug treatment with Diltiazem 2% gel), and the study was conducted at Tishreen University Hospital in Latakia – Syria, in the period between 2019-2020. **Results:** In group A, complete recovery occurred in 29 patients (96.6%), anal bleeding decreased in all patients (100%), pain feeling decreased in all patients (100%), and gas incontinence occurred only in 4 patients (13.3%). Fecal incontinence didn't occur. In group B, complete recovery occurred in 17 patients (56.6%), anal bleeding decreased in 17 patients (68%), pain feeling decreased in 17 patients (65.3%), and gas / fecal incontinence didn't occur at all. **Conclusion:** Lateral internal Sphincterotomy is still the first line of treatment in patients with a chronic anal fissure, but drug therapy with (Diltiazem 2% gel) can be applied to patients who refuse surgical treatment, or for those who have contraindications for surgical intervention.

KEYWORDS: Anal Fissure, lateral sphincterotomy, Topical diltiazem.

INTRODUCTION

An anal fissure is one of the most common lesions to be considered in the differential diagnosis of anal pain. The commonly accepted definition of an anal fissure is "A linear ulcer of the anoderm, distal to the dentate line, generally located in the posterior midline".[1-4] It typically causes episodic pain that occurs during defecation and persists for 1 to 2 hours afterward.[5] The most consistent finding in typical fissures is the spasm of the internal anal sphincter, which is so severe that the pain caused by the fissure is thought to be due to ischemia of the sphincter.[6] Chronic fissures, by definition, are those that persist beyond six weeks. The pathogenesis is not fully clear,[7] though reduced consumption of dietary fiber and constipation may be important risk factors.[8] Another hypothesis, supported by both anatomical and anal manometry studies, is that the relative ischemia of the posterior midline anal canal leads to poor healing of the fissure.[9]

Regarding the treatment aspect, there are two options, Conservative method which is most readily accepted by patients, and Secondly, surgical method of treatment,[10] The American Society of Colon and Rectal Surgeons (ASCRS) recommend conservative management with stool softeners, high fiber diet and sitz bath as the initial line of management.[11] A Cochrane review of anal fissure treatment had shown that topical and injected therapies are only marginally effective to placebo therapy and recommended lateral internal sphincterotomy (LIS) as the gold standard for chronic anal fissure (CAF).[12] The main drawback of LIS is the potential complication of incontinence to flatus or fecal matter. This is the reason for trying alternative pharmacologic agents (chemical sphincterotomy) in the treatment of CAF. An evidence-based summary

regarding the role of topical diltiazem had been recently issued by the National Institute for Health and Care Excellence (NICE, UK) organization in the UK.[13]

The aim of this randomized study was to compare the efficacy of topical 2 % diltiazem with the traditional LIS in the treatment of CAF.

METHODS

This was a hospital-based prospective study containing 2 groups, group A, where patients will be treated with the surgical approach and group B with the conservative approach. The study was carried out at the Department of General Surgery, at Tishreen University Hospital in Latakia – Syria, over a period of one calendar year, from September 2019 - September 2020. All patients presenting to the outpatient department of General Surgery, Tishreen University Hospital in Latakia – Syria, with symptoms of anal fissure were examined thoroughly, and a detailed history was taken as per the proforma.

Inclusion criteria

1. Patients with a confirmed diagnosis of chronic anal fissure.
2. Patients' age ranging from 18years to 50years of both the sexes.
3. Patients were willing to be part of the present study.

Exclusion criteria

1. Patients with co-morbidities of severe nature.
2. Age <18years and >50years.
3. Patients were not willing to be part of the present study.
4. Patients who were bedridden and were not able to participate in the present study.
5. Pregnant women.

During the study period, a total of 60 patients were selected, matching the inclusion and exclusion criteria. After the history and general examination, the local examination was carried out, which included the digital rectal examination to assess the extent and the degree of the anal fissure. These patients were randomly assigned to group A and group B with 30 patients for each group. Group A patients were treated on an in-patient basis. They were operated on using the lateral internal sphincterotomy method. Group B patients were treated for anal fissure on an outpatient base, and they were given 2% topical diltiazem with application instruction. All patient were they were asked to apply it twice a day foreight8 weeks.

All Patients were included after providing a written informed consent.

Follow up

All patients were followed for ten weeks in the outpatient clinic and a physical exam was performed with subjective data provided by the patients, and an outcome like flatus incontinence and fecal incontinence was noted in both the group patients.

Statistical analysis

The data were expressed as proportions and means. Chi-square test and students T-test was used to determine the efficacy of the treatment groups.

RESULTS

Both groups were comparable in terms of the distribution of males and females in the present study. The p-value was more than 0.05. The number of males and females in both groups was also not much different from each other. So, annal fissure can affect both sexes equally.

Both groups were comparable in terms of average age in the present study. The mean age in group A patients was 26.56 years, and the mean age of patients from group B was 25.96 years. The difference was statistically, not significant.

Symptoms

Both Pain and Bleeding per rectum were the most common presenting symptoms in both the groups affecting about 90% of the patients. Hence pain, bleeding were the presenting symptoms in the present study for patients from both the groups. Both groups were comparable in terms of symptoms.

Posterior midline anal fissure was seen in all patients.

Comparison of Healing in Both Groups at Different Weeks of Follow Up

Healing at 10th week was significantly higher in surgical treatment group A (96.6 %) than that of in medical treatment group B (56.6%). The p-value was less than 0.05.

Comparison of Pain Relief in Both Groups at Different weeks of Follow Up

Pain relief was more in the surgical treatment group than in the medical treatment group at the 10th week of follow up. Significant pain relief was seen in both the groups as duration progresses from 2nd to 10th week.

Comparison of Bleeding PR in Both Groups at Different Weeks of Follow Up

Bleeding PR has regressed more in the surgical treatment group than in the medical treatment group at the 10th week of follow up. Significant regression of bleeding was seen in both the groups as duration progresses from 2nd to 10th week.

Comparison of incontinence incidence in Both Groups

No incontinence was present in the medical treatment group (B) throughout the study period. But four patients among surgical treatment group (A) had gas incontinence in 2nd week, and by the end, the of 10 end them, all of them were healed.

Table 1: Distribution as per sex.

Sex	Group		Chi-square	P-value
	A	B		
Males	17 (56.66%)	16 (53.33%)		
Females	13 (43.33%)	14 (46.66%)	0.0673	0.795

Table 2: Comparison of the mean age between the two groups.

Group	Mean	SD	T - value	P-value
A	26.56	4.95	0.41	0.68
B	25.96	6.13		

Table 3: Comparison of symptoms between the two groups.

Symptoms	Group	
	A	B
Anal pain	28 (93.3%)	26 (86.6%)
Bleeding PR	27 (90%)	25 (83.3%)
Anal Itching	20 (66.6%)	19 (63.3%)
Anal Oozing	21 (70%)	23 (76.6%)
Constipation	18 (60%)	20 (66.6%)

Table 4: Comparison of healing rates between the groups

Time of follow up	Group		Chi-square	P-value
	A	B		
2^{nd} week	12 (40%)	1 (3%)	11.882	0.0005
6^{th} week	20 (66.6%)	9 (30%)	8.075	0.0044
10^{th} week	29 (96.6%)	17 (56.6%)	13.416	0.0002

Table 5: Comparison of pain relief between the groups.

Time of follow up	Group		Chi-square	P-value
	A	B		
2nd week	12 (42.8%)	1 (3%)	11.224	0.0008
6th week	20 (71.4%)	9 (34.6%)	7.348	0.006
10th week	28 (100%)	17 (65.3%)	11.63	0.0006

Table 6: Comparison of bleeding PR regression between the groups.

Time of follow up	Group		Chi-square	P-value
	A	B		
2^{nd} week	12 (44.4%)	1 (4%)	11.324	0.0007
6^{th} week	20 (74%)	9 (36%)	7.628	0.0057
10^{th} week	27 (100%)	17 (68 %)	10.219	0.0013

Table 7: Comparison of incontinence incidence in Both Groups.

Type	Group		Chi-square	P-value
	A	B		
Flatus incontinence	4 (13.3%)	-	4.285	0.0384
Fecal incontinence	-	-	-	-

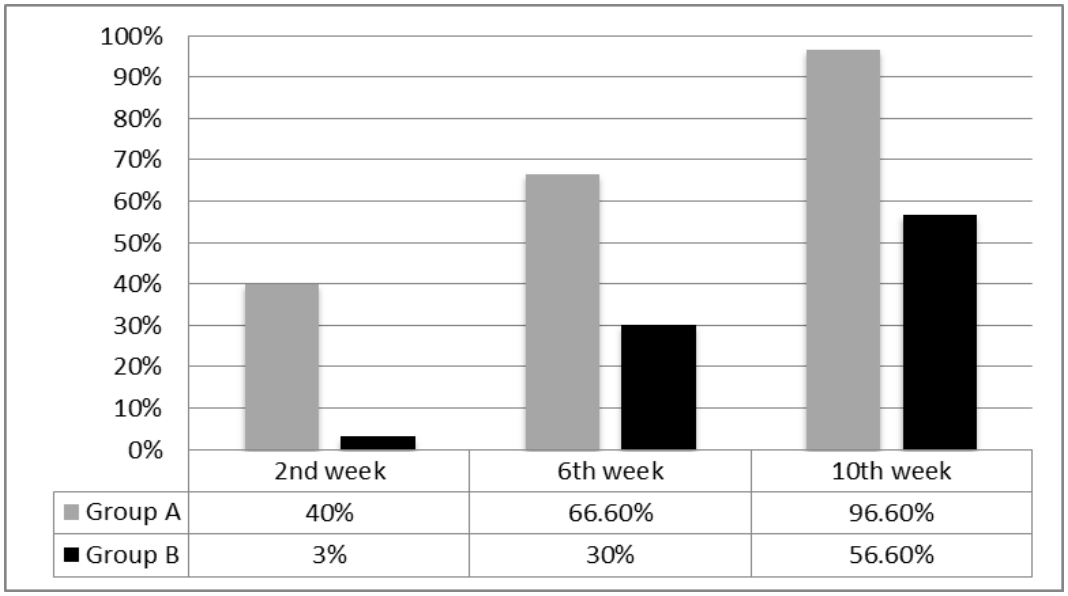

Figure-1: Comparison of healing rates between the groups.

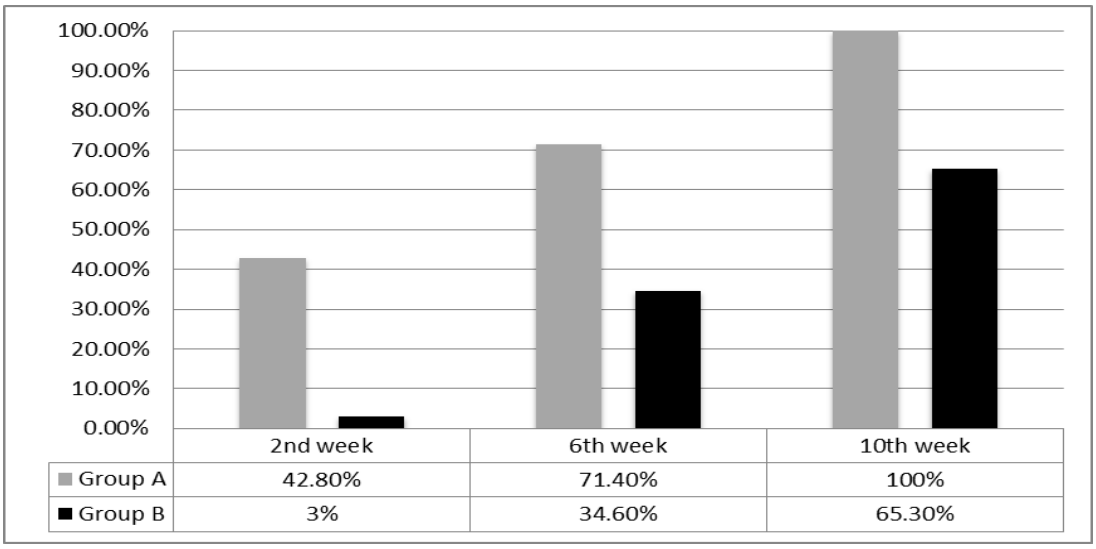

Figure 2: Comparison of pain relief between the groups.

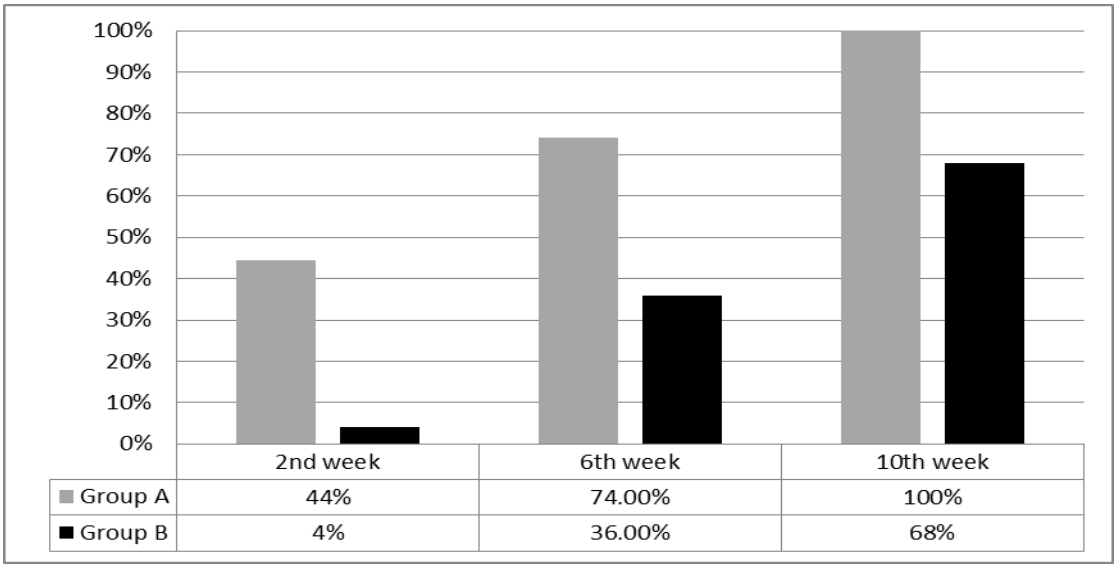

Figure 3: Comparison of Bleeding PR regression between the groups.

DISCUSSION

Anal fissure is a very common problem across the world. It causes considerable morbidity and adversely affects the quality of life. Anal fissure is usually encountered in young or middle aged adults.[14,15] and is equally common in both sexes.[14] It is commonly found in the posterior position, although anterior fissure is comparatively common in females.[16]

Therapy focuses on breaking the cycle of pain, spasm, and ischemia thought to be responsible for the development of fissure in ano. Operative management includes anal dilatation and lateral internal sphincterotomy. Lateral sphincterotomy is perhaps the operation of choice to perform in patients with chronic anal fissure needing surgical treatment. Postoperative management is simple and rate of healing is faster. However complication such as permanent anal incontinence is associated with the surgery. Chemical sphincterotomy is now the first line of treatment in many centers.[17-19] Calcium channel blockers like nifedipine and diltiazem have been shown to lower resting anal pressure,[20] promote fissure healing and are associated with good healing rate,[17,21,22] They are associated with side effects such as headache and perianal dermatitis.[17]

Knight et al. 2001,[23] from the UK observed that 75% of their cases had fissure healed with topical 2% diltiazem-ointment. Giridhar et al. 2014,[24] reported a healing rate of 88.46% in 4 weeks, with 2% diltiazem gel and a 100% healing rate by four weeks with LIS. Vaithiananthan R et al. 2015,[25] explored the role of diltiazem as an alternative to surgical intervention in patients with a fissure in ano.9 They found that in the diltiazem group, the healing rate was 71% compared to 96% in the surgery group. Abhivardan D et al. 2017,[26] carried out a prospective study in 80 patients and assigned 40 patients each randomly in two groups; one group with diltiazem and the other group patients underwent surgery. They noted that in the diltiazem group, 37 out of 40 patients had complete healing. In this diltiazem group, only three patients had a recurrence. They concluded that 2% diltiazem should be preferred only for acute fissure in ano, and for the management of the chronic fissure in ano, surgery is better than topical diltiazem. In a study by Gupta et al. 2018,[27] anal bleeding decreased by 93.3% in patients with surgical treatment, compared to 56.6% of medical treatment patients. Babu et al. 2016,[28] reported that bleeding PR has regressed in 91.4% of patients with surgical treatment, compared to 85.7% of medical treatment patients. Acar et al. study 2020,[29] showed the percentage of anal pain reduction in surgically treated patients of 91%, compared to 68% in medically treated patients. Pain relief of 100% in the surgical treatment group and 83% in the medical treatment group was reported in Motie et al. 2015.[30] While in Gupta et al. 2018,[27] the percentage of anal pain reduction in surgically treated patients was 96%, and the rate among medically treated patients was 56.6%. Yucel et al. 2009,[31] observed that rectal bleeding improved in 84.6% of patients who underwent surgery. Flatus incontinence occurred in 1% and 8.5% of the surgically treated patients without fecal incontinence, and flatus incontinence did not occur at all in drug-treated patients as reported by Babu et al and Acar et al. and. Respectively,[28-29]

In our study, we found that the healing rate was 96.6% in the surgical group compared to 56.6% in the diltiazem group, bleeding PR decreased by 100% in Group A patients, and in 68% of group B patients ,pain relief was 100% in group A, compared to 65.3% in group B, and we observed that the rates of anal pain regression after treatment with the surgical intervention were higher than drug-treated patients with a statistically significant difference ($P < 0.05$), at all times. Flatus incontinence occurred in 13.3% of group A patients, while they had no fecal incontinence, and in group B, gas incontinence did not occur at all .The incidence of gas incontinence in patients treated with the surgical intervention was higher than in drug-treated patients by a statistically significant difference ($P < 0.05$).

CONCLUSION

Lateral Internal Sphincterotomy is found to be a better treatment modality for chronic Fissure-in-Ano Topical Diltiazem ointment in this study. However, Topical Diltiazem ointment can be used as the initial modality of treatment in patients unwilling or unfit for surgery.

REFERENCES

1. Cross KL, Massey EJDA, Fowler AL, Monson JRT.The management of anal fissure: ACPGBI position statement.Colorectal Dis., 2008; 10(Suppl3): 1-8. doi:10.1111/j.1463-1318.2008.01681.x.[Pubmed].
2. Orsay C, Rakinic J, Perry Brian W, et al. ASCRS practical parameters for the management of anal fissures. Dis Colon Rectum, 2004; 47: 2003–2007. doi: 10.1007/s10350-004-0785-7.
3. CKS/NHS Anal fissure, http://www.cks.nhs.uk /anal_fissure#-314748.
4. Lund JN, Scholefield JH. Etiology and treatment of anal fissure. Br J Surg, 1996; 83: 1335–1344. doi: 10.1002/bjs.1800831006. [PubMed] [Cross Ref].
5. Richard LN. Medical treatments are only marginally better than placebo, but surgery may cause incontinence. BMJ., 2003; 327: 354e355.
6. Schouten WR, Briel JW, Auwerda JJ. Relationship between anal pressure and anodermal blood flow. The vascular pathogenesis of anal fissures. Dis Colon Rectum, 1994; 37: 664e669.
7. Uwe W Pharmacological sphincterotomy for chronic anal fissures with the use of the botulinum toxin A. J Cutan Aesthet Surg, 2008; 1: 58–63.
8. Jensen SL Diet and other risk factors for fissure-in-ano. A prospective case-control study. Dis Colon Rectum, 1988; 31: 770–773.

9. Rankinic J Anal fissure. Clin Colon Rectal Surg, 2007; 20: 133–138.
10. Nelson R. Operative procedures for Fissure-in-Ano. Cochrane Database Syst Rev., 2002; 1: CD002199.
11. Perry WB, Dykes SL, Buie WD, Rafferty JF Standards practice task force of the American Society of Colon and Rectal Surgeons Practice parameters for the management of anal fissures(3rd. revision). Dis Colon Rectum, 2010; 53: 1110–1115.
12. Nelson RL, Chattopadhyay A, Brooks W, Platt I, Paavana T, EarlS Operative procedures for fissure in ano. Cochrane Database Syst Rev, ;2011 (11): Art. No.: CD002199. doi:10.1002/14651858.CD002199.pub4.
13. Publications.nice.org.uk. 2013. ESUOM3: Chronic anal fissure: 2% topical diltiazem hydrochloride key… ESUOM3. [online] Available at: http://publications.nice.org.uk/esuom3-chronic-anal-fissure-2- topical-diltiazem-hydrochloride-esuom3. Accessed Dec 13, 2013.
14. John Goligher, Anal Fissure, John Goligher, Surgery of the Anus, Rectum& Colon. AITBS, 5th Edition, 1992; 150.
15. Udwadia T.E., The prophylaxis of fissure in ano. Indian Journal of Surgery, 1960.
16. Boulos PB, Araujo JGC, Adequate internal sphincterotomy for chronic anal fissure: subcutaneous or open technique? British Journal of Surgery, 1984.
17. J. S. Knight, M. Birks, R. Farouk, Topical Diltiazem ointment in the treatment of chronic anal fissure. British Journal of Surgery, 2001; 88(4): 553-56.
18. R. Bhardwaj, M. C. Parker, Modern perspectives in the treatment of chronic anal fissures. Annals of the Royal College of Surgeons of England. 2007; 89(5): 472-78.
19. Z Haq, M Rahman, RA Chowdhury, MA Baten, M Khatun, Chemical sphincterotomy – first line of treatment for chronic anal fissure. Mymensingh Medical Journal, 2005; 14(1): 88-90.
20. E Carapeti, M Kamm, B Evans, R Phillips, Topical Diltiazem and Bethanechol decrease anal sphincter pressure and heal anal fissures without side effects. Diseases of the Colon and Rectum, 1999; 43(10): 1359-62.
21. UK Srivastava, BK Jain, Praveen Kumar, Yusuf Saifee. A comparison of the effects of Diltiazem and Glyceryl trinitrate ointment in the treatment of chronic anal fissure: a randomized clinical trial. Surgery Today, 2007; 37(6): 482-85.
22. GF Nash, K Kapoor, K Saeb-Parsy, T Kunanadam, PM Dawson, The long term results of Diltiazem treatment for anal fissure. International Journal of Clinical Practice, 2006; 60(11): 1411-13.
23. Knight JS, Birks M, Farouk R. Topical diltiazem ointment in the treatment of chronic anal fissure. Br J, 2001.
24. Giridhar C M, Babu P, Rao KS. A comparative study of lateral sphincterotomy and 2% diltiazem gel local application in the treatment of chronic fissure in ANO. J Clin Diagn Res., 2014; 8: NC01-2.
25. Vaithianathan R, Panneerselvam S. Randomised prospective controlled trial of topical 2% diltiazem versus lateral internal sphincterotomy for the treatment of chronic fissure in ano. Indian J Surg, 2015 Dec 1; 77(3): 1484-7.
26. Abhivardan D, Sivakumar VV, Rama Rao K, Balaji K, Sujatha M, Ramu L. A comparative study between 2% diltiazem application versus lateral sphincterotomy in a fissure in ANO. Int J Contemporary Med Res, 2017; 4(3): 751-2.
27. M.Gupta, V. S. Prasad, A.Kumar, D.Sinha. A Comparative Study To Evaluate The Effectiveness And Complications Associated With Topical Diltiazem Versus 0pen Partial Lateral Internal Anal Sphincterotomy For Chronic Anal Fissure. IOSR-JDMS, 2018; 17(9): 13-18.
28. S.M.Babu, A Singh, R.Gupta, A.P.S.Gaharwar. Comparative Study of Lateral Internal Sphincterotomy and Diltiazem 2% Topical Ointment in the Treatment of Chronic Fissure in Ano: A Prospective Study. IJSS Journal of Surgery, 2016; 2: 6.
29. T Acar, N Acar, F Güngör, E Kamer, H Genç, K Atahan, ON Dilek, M Hacıyanlı. Comparative Efficacy of Medical Treatment Versus Surgical Sphincterotomy in the Treatment of Chronic Anal Fissure. Nigerian Journal of Clinical Practice, 2020; 23: 4.
30. M.Motie, P.Hashemi. Chronic Anal Fissure: A Comparative Study of Medical Treatment Versus Surgical Sphincterotomy. Acta Medica Iranica, 2016; 54.
31. Yucel T, Gonullu D, Once M, Koksoy FN, Ozkan SG, Aycan O. Comparison of controlled-intermittent anal dilatation and lateral internal sphincterotomy in the treatment of chronic anal fissures: A prospective, randomized study. Int J Surg, 2009; 7: 228-31.